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Signed Stephen Hordley

Dated 30 November 2004

Patents Form 1/77

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
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1. Your reference — P34789-/CMU/RTH/RMC

2. Patent application number *(The Patent Office will fill in this part)* — 0325442.2

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

   Mpathy Medical Devices Limited
   6.05 Kelvin Campus
   West of Scotland Science Park
   Glasgow
   G20 0SP

   Patents ADP number *(if you know it)* 08730905001

   If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — "Plug"

5. Name of your agent *(if you have one)* — Murgitroyd & Company

   "Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

   Scotland House
   165-169 Scotland Street
   Glasgow
   G5 8PL

   Patents ADP number *(if you know it)* ~~1198013~~ 1198015

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

   a) any applicant named in part 3 is not an inventor, or
   b) there is an inventor who is not named as an applicant, or
   c) any named applicant is a corporate body.
   See note (d))

   Yes

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	17
Claim(s)	-
Abstract	-
Drawing(s)	6 + 6

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Murgitroyd & Company. Date 30 October 2003

Murgitroyd & Company

12. Name and daytime telephone number of person to contact in the United Kingdom: ROISIN MCNALLY 0141 307 8400

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.*

b) *Write your answers in capital letters using black ink or you may type them.*

c) *If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.*

d) *If you have answered 'Yes' Patents Form 7/77 will need to be filed.*

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"Plug"

The present invention relates to a device for bodily hernia repair, particularly, but not exclusively, to a plug device for inguinal hernia repair or femoral hernia repair.

Hernias are due to an abnormal protrusion of an organ or part thereof through its containing structure, due to a rupture or weakening in a layer of fascia creating an aperture or a defect in the fascia which causes it to be less able to contain the organ or part thereof.

Hernias can occur at various anatomical positions in the abdomen where there is a weakness in the muscle, and are classified according to the site in which they occur.

Two particular types of hernia are inguinal hernias and femoral hernias.

Inguinal hernias occur in the groin when a portion of bladder, bowel or membrane pushes through a weak spot in the abdominal musculature around or at the inguinal canal. The inguinal canal is an opening between layers of abdominal muscle near the groin through which the spermatic cord passes in the male. Typically, inguinal hernia is a male condition.

Two particular types of inguinal hernias occur, direct inguinal hernias and indirect inguinal hernias.

An indirect inguinal hernia passes through the internal ring of the inguinal canal, along the canal and, if the hernia is large enough, emerges through the external ring and in the male descends into the scrotum.

A direct inguinal hernia differs from an indirect inguinal hernia as it pushes its way directly forwards through the posterior wall of the inguinal canal. Occasionally, in unusual circumstances, a direct hernia becomes large enough to push its way through the external ring and then into the neck of the scrotum.

The femoral artery and vein enter the femoral triangle from beneath the inguinal ligament within a fascial tube termed the femoral sheath. The femoral canal is a small, almost vertically-placed gap in the medial part of the femoral sheath. The femoral canal is a potential point of weakness in the

abdominal wall which may develop a femoral hernia. The canal is around 1 to 1.5 cm in length. As the female pelvis is of greater width than the male pelvis the femoral canal can be somewhat larger in females and female femoral hernias are more common. A femoral hernia is a protrusion through the femoral canal. The hernia sac may extend through the femoral canal.

Hernia repair generally requires the contents of the hernia to be eased back into position and then for the weakened area to be repaired. Repair can be effected by tension or tension-free suturing of the tissue and muscle to strengthen the weakened area or occlude ruptured areas. Alternatively the weakened or ruptured area can be reinforced using a portion of synthetic mesh.

Meshes for use in the treatment of an inguinal or femoral hernia typically consist of a flat portion of mesh for application over the hernia area. The mesh allows a tension free repair to be made of the weakened area.

Alternatively for a well circumscribed defect, e.g. a deep inguinal hernia or femoral hernia, the repair device may be a plug which stops the rupture hole of the hernia.

Plug devices of the prior art include the Bard PERFIX plug ™, Ethicon's Prolene Hernia System ™, and Surgipro Hernia Mate plug and Patch ™ or Atrium

Self-forming plugs ™. The Bard PERFIX plug ™ is one of the most popular plugs and comprises around 8 leaves or petals, which are joined in a central region. The central portion of the plug is pushed into the defect and the leaves trimmed according to the size of the defect such that they stop the defect. As the leaves project from the central portion these aid the retention of the plug in the defect. In addition, an overlay patch may be positioned over the plug which surrounds those tissues surrounding the inguinal canal. Surgipro Hernia Mate plug and Patch ™ and Atrium Self-forming plugs ™ also comprise several leaves and an overlay patch and work in a similar fashion to the Bard product.

Ethicon's Prolene Hernia System ™ comprises a first overlay patch for placing around the inner ring of the inguinal canal a central portion and a second overlay patch for placing around the outer ring of the inguinal canal. The central portion corresponds to both a portion of the first and second overlay patches such that it is held in the inguinal canal by the two patches to block the canal.

In use, the plugs of the prior art block the inguinal canal and prevent a hernia sac from protruding through the canal. The defects blocked by the plugs are substantially circular in cross section. However, anatomical structures which under normal circumstances pass through the inguinal canal, such as the spermatic cord, protrude at the

edge of the plug. In conventional plugs these anatomical structures are compressed between the plug and the surrounding tissue. This can lead to discomfort for the patient and might lead to long term damage to the structure(s) being compressed and may cause ischaemia of a distal organ, for example where the anatomical structure includes the spermatic cord ischaemia of the testes may occur as a result of compression of the artery and/or vein along with the spermatic cord.

According to the present invention there is provided a prosthesis for hernia defect occlusion comprising a plug having at least an outer surface and an inner surface wherein, in a side of the plug, the inner surface forms a channel through which, in use, an anatomical structure may pass when the plug is in place in the body without substantial compression of said anatomical structure.

An advantage of a prosthesis of the present invention is that by providing such a passage in the prosthesis, damage and discomfort caused by compression of anatomical structures passing through the defect being repaired can be minimised, while minimising the rupture or protrusion of a hernia sac through the defect/canal, such as the inguinal or femoral canal.

Preferably the prosthesis has a truncated conical shape. Preferably the inner surface defines a scalloped channel.

A prosthesis of truncated conical shape in which a first end of the prosthesis has a diameter less than that of a second end has the advantage that the prosthesis can be pushed first end into the defect/canal, to plug the defect/canal, more easily.

It is preferable that the channel has a substantially semi-circular edge in cross section, such that the inner surface is substantially curved as it interfaces with the anatomical structure which the channel receives. However, it will be understood that the edge of the channel may include at least one straight portion such that the inner surface has a straight portion in cross section, for example a box section channel.

Preferably the prosthesis is formed from resilient material such that the prosthesis can be flexed to open the access to the channel.

This is advantageous in that the channel may be formed such that, in use, the prosthesis may be flexed from its rest position to an open position to increase the width of the access to the channel enabling the anatomical structure to be more easily received by the channel and then the prosthesis may be released to return to the rest position wherein the anatomical structure is substantially enclosed by the channel when the prosthesis is located in the defect.

In certain preferred embodiments the channel is capable of receiving a spermatic cord.

In alternative embodiments, the channel is capable of receiving a femoral vein, or other anatomical structures.

Preferably the channel is sized such that, in use, the anatomical structure which passes through the channel is not substantially compressed. In one embodiment, substantial compression of the anatomical structure is compression which causes pain to the patient or ischaemia of a distal organ. Preferably the width of the anatomical structure, which in use passes through the channel, is compressed less than 70%, even more preferably less than 50%, yet preferably less than 40%, even more preferably less than 30%, even more preferably less than 20%, yet more preferably less than 10%, even more preferably less than 5%, even more preferably less than 3%, most preferably less than 1% by the channel of the plug.

As prior art devices are pushed into the aperture and can trap an anatomical structure between the exterior of the prior art device and the tissue surrounding the aperture, a significant pressure may be experienced by an anatomical structure. Significant pressure is pressure which causes distortion, compression or full or partial collapse of an anatomical structure. For example, in particular examples where a conventional plug is

used to treat inguinal hernia, the spermatic cord is squeezed between the plug and the tissues surrounding the aperture and this squeezing may cause pain or even damage to the spermatic cord.

Preferably the level of compression experienced by the anatomical structure by the prosthesis of the present invention when the anatomical structure passes through the channel of the prosthesis is not more than venous pressure. Venous pressure is typically between 2 to 10 mm Hg.

Preferably the prosthesis has a single channel. In another embodiment the prosthesis can include two channels. Each channel may be sized to receive at least one anatomical structure in order to maximise the support provided by the prosthesis while allowing the structure(s) to pass through the one or more defined channels in the prosthesis.

In particular embodiments the prosthesis may comprise a plurality of channels on its surface. The provision of a plurality of channels may be advantageous as different anatomical structures may be received by the prosthesis at different points around the surface of the prosthesis.

In a preferred embodiment of the present invention the prosthesis comprises a flange provided on either one or both ends of the prosthesis. The provision of a flange on the prosthesis is advantageous as it aids location of the prosthesis in the body and may

provide additional support to tissue surrounding the defect. In particular embodiments, the flange is mounted on the prosthesis such that, in use, the flange provides an inferomedial extension to the prosthesis. For example, if the prosthesis is used to plug an inguinal canal, one end of the prosthesis is positioned at the internal inguinal ring of the inguinal canal and a second end is positioned at the external ring of the inguinal canal and a flange can inferomedially extend from the external ring.

Preferably the flange is a portion of synthetic mesh.

This is advantageous as a flange constructed of mesh has minimal mass density in relation to its volume.

The flange portion may contain structures or regions capable of receiving sutures or other fixing means to secure the flange around the anatomical structures received by the channel and/or to the surrounding tissue.

Preferably the prosthesis is constructed of mesh, solid material, foam or hydrogel. In particular embodiments the prosthesis is formed from rolls of mesh and/or comprises cross members to provide the prosthesis with strength to resist compression. In particular embodiments the mesh or solid material may be formed from plastics material. In particular embodiments the foam is formed from polyurethane.

In preferred embodiments the prosthesis has a crenated outer surface. The crenated surface allows the prosthesis to grip the tissues surrounding the prosthesis and aids retention of the prosthesis in position.

Preferably the prosthesis has a longitudinal length or depth of between 1 to 5 cm. More preferably the prosthesis has a longitudinal length in the range of between 2 to 3 cm.

In embodiments wherein the plug has a truncated conical shape the diameter of the widest end of the prosthesis is preferably between 2 to 7 cm and the diameter of the narrowest end is preferably between 0.5 to 4 cm.

The channel receiving the anatomical structure can have any suitable cross sectional shape such as a semi-circular cross section. Preferably the channel is between 0.5 cm to 3 cm in width and depth or where the channel is of circular or substantially circular cross section, for example semi-circular cross section, the channel is between 0.5 cm to 3 cm in diameter.

Embodiments of the present invention will now be discussed, by way of example only, with reference to the accompanying figures in which;

Figure 1 shows a perspective view of an embodiment of a prosthesis of the invention

from one end;

Figure 2 shows a perspective view of an embodiment of a prosthesis of the invention from the other end;

Figure 3 shows a perspective view of an embodiment of a prosthesis of the invention in use;

Figure 4 shows an indirect inguinal hernia;

Figure 5 shows a hernia repaired using a device of the prior art;

Figure 6 shows an embodiment of a prosthesis which further includes a flange provided at one end of the prosthesis of the invention;

Figure 7 shows an illustration of the anatomy around the inguinal canal; and

Figure 8 shows an illustration of the anatomy around the femoral canal.

The prosthesis has application to plug or stop any aperture in the body in which a structure is required to pass through or adjacent to the aperture. For example, the prosthesis can be used to plug the inguinal canal or the femoral canal.

As shown in figure 1, in one embodiment, the

prosthesis 10 is a truncated cone of mesh material wherein the inner surface is defined by a substantially scalloped portion 12 formed by an open edged cylindrical (scalloped) channel 13 removed from the outer conical surface of the cone such that a prosthesis 10 of crescent cross section is provided.

As shown in figures 1 and 2 the prosthesis has a first end 14 which, in use to plug an inguinal canal, is positioned at the internal inguinal ring of the inguinal canal. In use, the second end 16 is positioned at the external ring of the inguinal canal.

The prosthesis has a channel 12 in the outer conical surface of the prosthesis capable of receiving an anatomical structure(s) which passes through the inguinal canal. The channel is in the range of 5 mm to 20 mm in width. Although in the embodiment shown in figures 1 to 3, the channel is substantially semi-circular in cross section, the channel may be of any shape. In addition, more than one channel may be present in the conical surface of the prosthesis, each channel being able to receive a particular anatomical structure.

Typically the prosthesis is between 1 to 5 cm in length between the ends and around 1 to 4 cm in diameter.

As shown in figure 3, in use, an anatomical

structure 30 is received by the channel 12, the channel indenting the conical surface of the prosthesis, the channel linking the ends 14,16.

In use the prosthesis of the present application can be pushed into the inguinal canal to contain the organs or parts being pushed through the inguinal canal and to minimise their protrusion through the inguinal canal.

In contrast to the devices of the prior art, anatomical structures, such as the spermatic cord, can be received by the channel 12 of the prosthesis such that such anatomical structures can pass from one end of the prosthesis to the other with minimal compression by the prosthesis.

As shown in figure 5, previous plugs to stop the inguinal canal have utilised plug devices which are pushed into the canal, but which do not have means to allow the passage of structures such as the spermatic cord through or around the plug. This means the anatomical structure, such as the spermatic cord, is therefore compressed between the plug and the surrounding tissue, which can lead to patient discomfort and potentially may damage the anatomical structure.

The prosthesis of the present invention may further comprise a flange or lip which protrudes laterally from the second end to aid the positioning of the device in the inguinal canal. The lip may be formed

from mesh and extend from the prosthesis such that in use the mesh can be used to support the musculature surrounding the inguinal canal. Thus in particular embodiments the prosthesis can include an inferomedial mesh extension. This allows the device of the present Application to be used in the treatment of direct inguinal hernias. A prosthesis of the present application may further include a flange 18 at the first end of the prosthesis. The prosthesis can be positioned into the inguinal canal and the flange used to support the tissue surrounding the canal.

As shown in figure 6, such a flange 18 or lip may comprise mesh material which extends laterally from the second end. In use, the tissue or fascia surrounding the inguinal canal can be supported using the mesh. It can be appreciated that the flange can be designed or cut to an appropriate size for either locating the prosthesis in the canal or to support surrounding tissue.

In a further embodiment a flange is provided on both ends of the prosthesis. In such an embodiment, if the flange is formed from a mesh material, the mesh can be provided around the internal ring and external ring of the inguinal canal such that the tissue and fascia around the inguinal ring is sandwiched between two layers of mesh. This supports the tissue and/or fascia and minimises the likelihood of organs or structures rupturing or protruding through the tissue and/or fascia.

Although figure 6 shows the flange extending away from the spermatic cord, the flange may extend in all directions from either end of the prosthesis. Where the flange extends in all directions, the flange may include a cut portion and aperture to enable the flange portion to be arranged around the anatomical structure such as the spermatic cord received by the channel.

In addition, the flange portion may contain structures or regions capable of receiving sutures or other fixing means to secure the flange around the anatomical structures received by the channel and/or to the surrounding tissue.

To aid the fixation of the prosthesis in the inguinal canal the prosthesis may be crenated on its exterior surface. Such crenations will project from the surface of the prosthesis into the surrounding tissue and minimise the movement of the prosthesis once it has been suitably positioned.

As shown in figure 8, the femoral canal, which is about 1 cm in length is located in the medial part of the femoral sheath. As discussed above, the femoral canal is a point of potential weakness in the abdominal wall through which a hernia may develop. A prosthesis of the present application can be inserted into the femoral canal to minimise the protrusion of the hernia sac through the femoral

canal while allowing the passage of anatomical structures through or into the prosthesis.

The function of the femoral canal is to firstly act as a dead space for expansion of the distended femoral vein and secondly as a lymphatic pathway from the lower limb to the external iliac nodes.

The channel of the prosthesis of the present application can be orientated such that expansion of the femoral vein is into the channel of the prosthesis and thus in contrast to plugs of the prior art, compression of the expanded vein against the side of the prosthesis will be minimised. In addition, the channel will still provide for movement in the lymphatic system from a lower limb to external iliac nodes. In one embodiment a prosthesis for use in plugging the femoral canal of the present invention is substantially of triangular prism shape. In another embodiment, in cross section, the prosthesis is substantially arrowhead shaped having two outer arcuate sides which extend from a base towards each other to form a point. Preferably the point is rounded. Alternatively the prosthesis is substantially D shaped with the arcuate sides forming a more rounded arched point. The base portion is preferably indented towards the point to receive an anatomical structure.

As discussed above, the prosthesis may further include a flange at either or both ends, which can extend around the femoral canal and thus support the

surrounding tissue or fascia. Such a flange may also contain cutouts to accommodate structures such as the femoral nerve and / or artery.

The prosthesis of the present application has been designed to take into consideration the anatomical structures and properties of the inguinal and femoral canal to minimise the disruption of these structures following location of the prosthesis.

Various modifications can be made without departing from the scope of the invention, for example, flanges extending from the faces of the prosthesis, as discussed above, may be formed from material with memory, such that following placement in the body the flanges move from a collapsed position to an extended position to secure the prosthesis in the body.

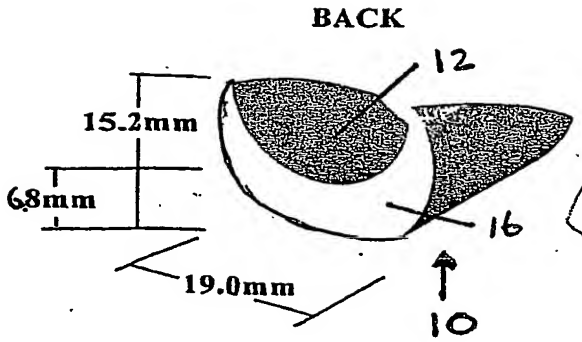


Figure 1

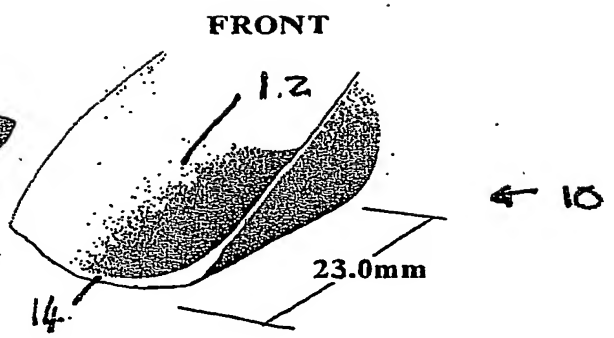


Figure 2

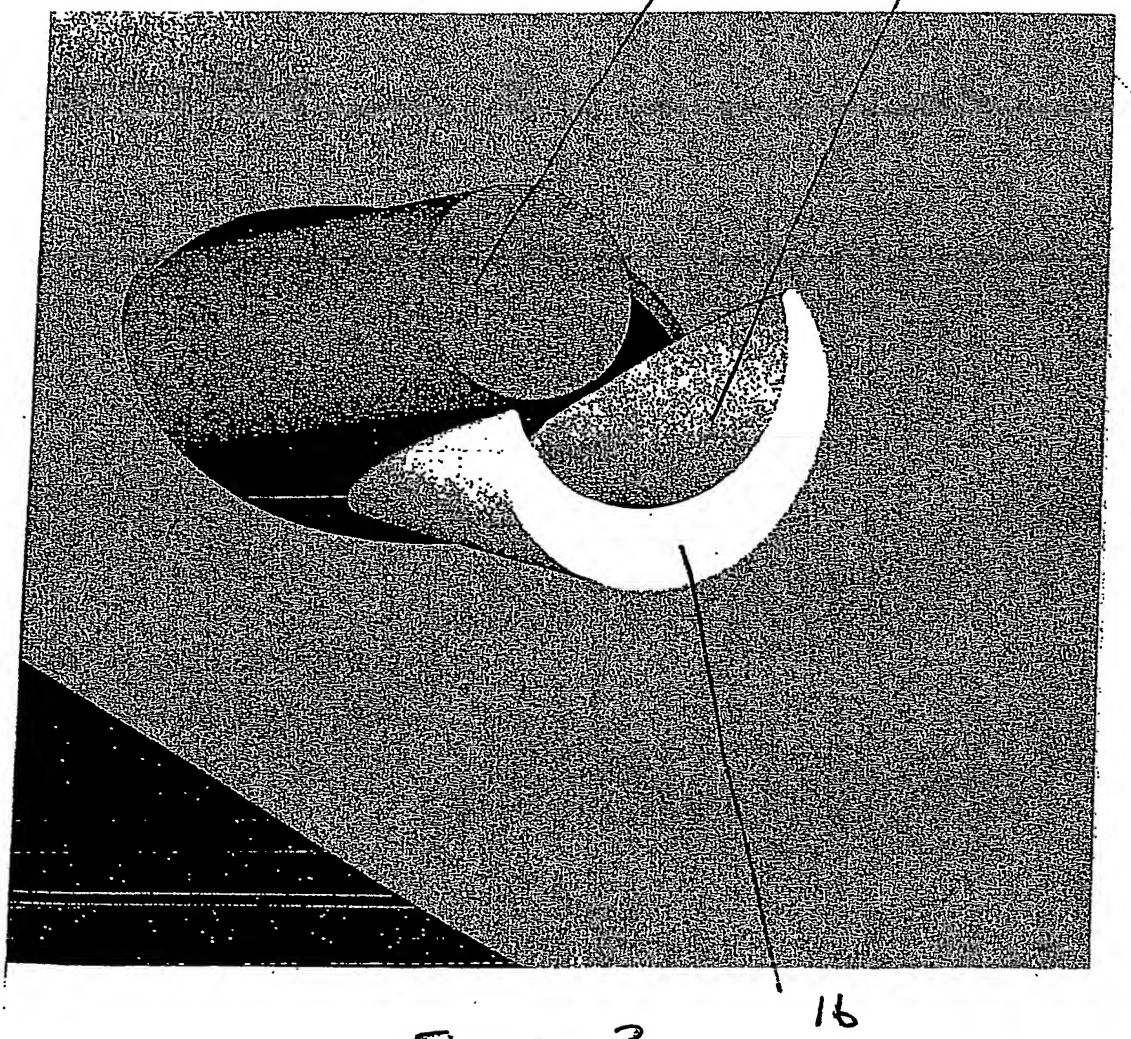
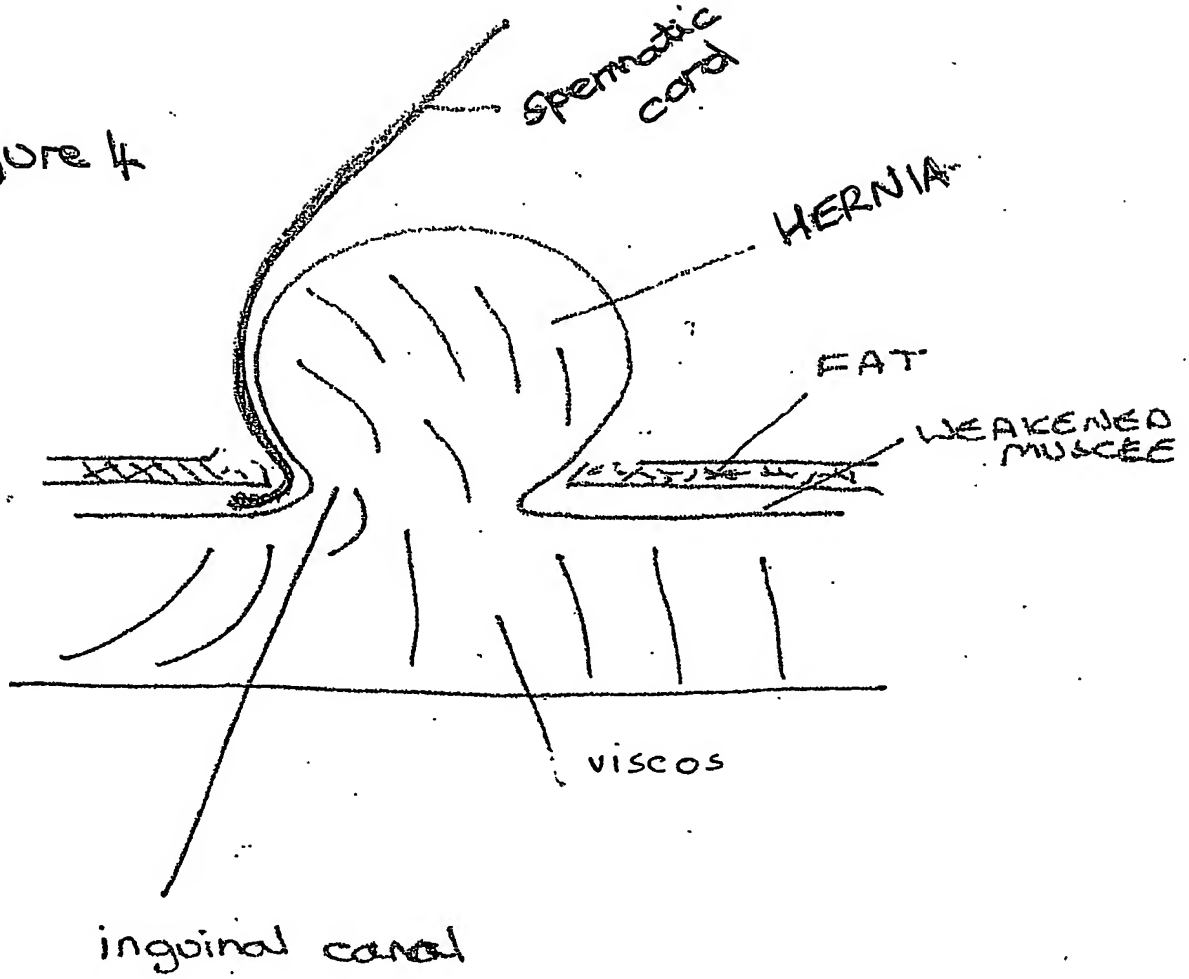


Figure 3

Figure 4



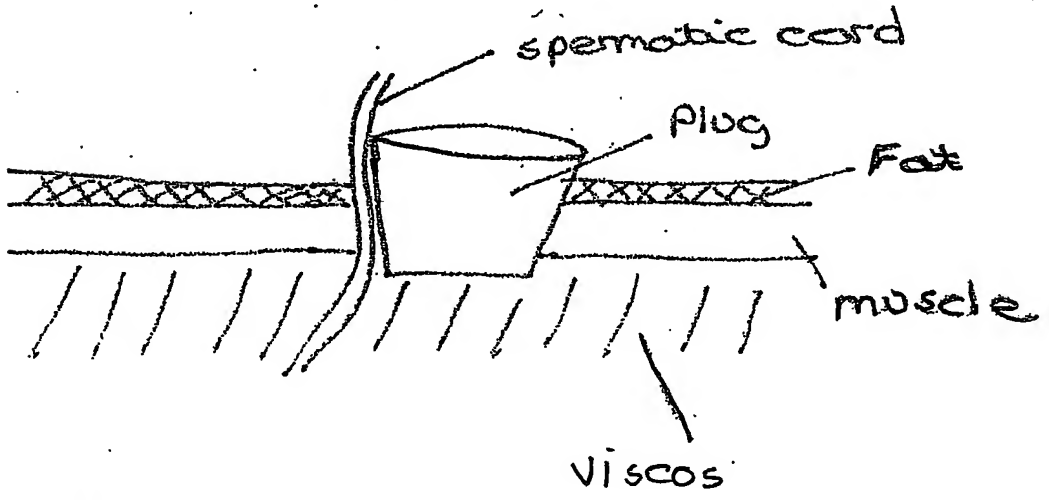


Figure 5

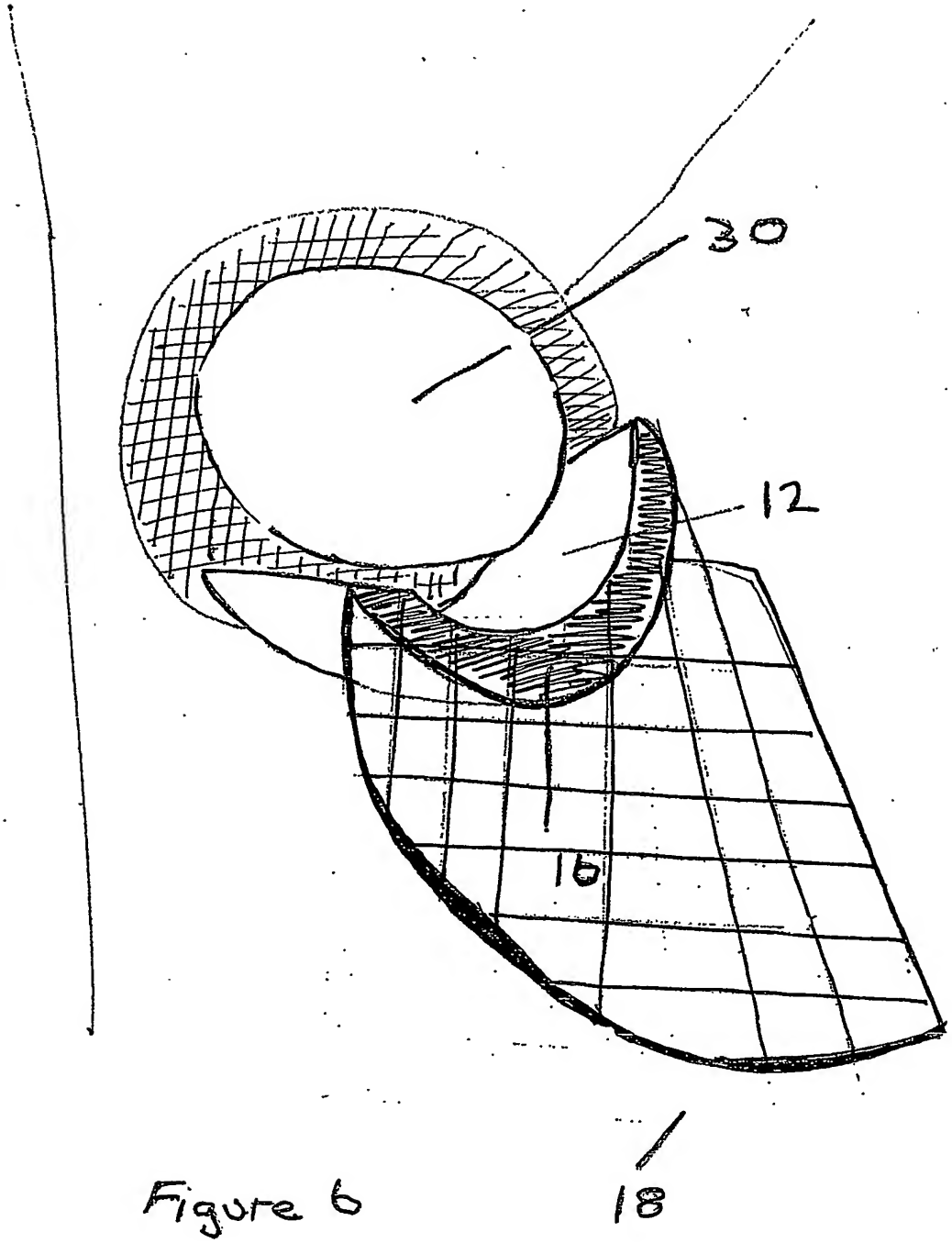
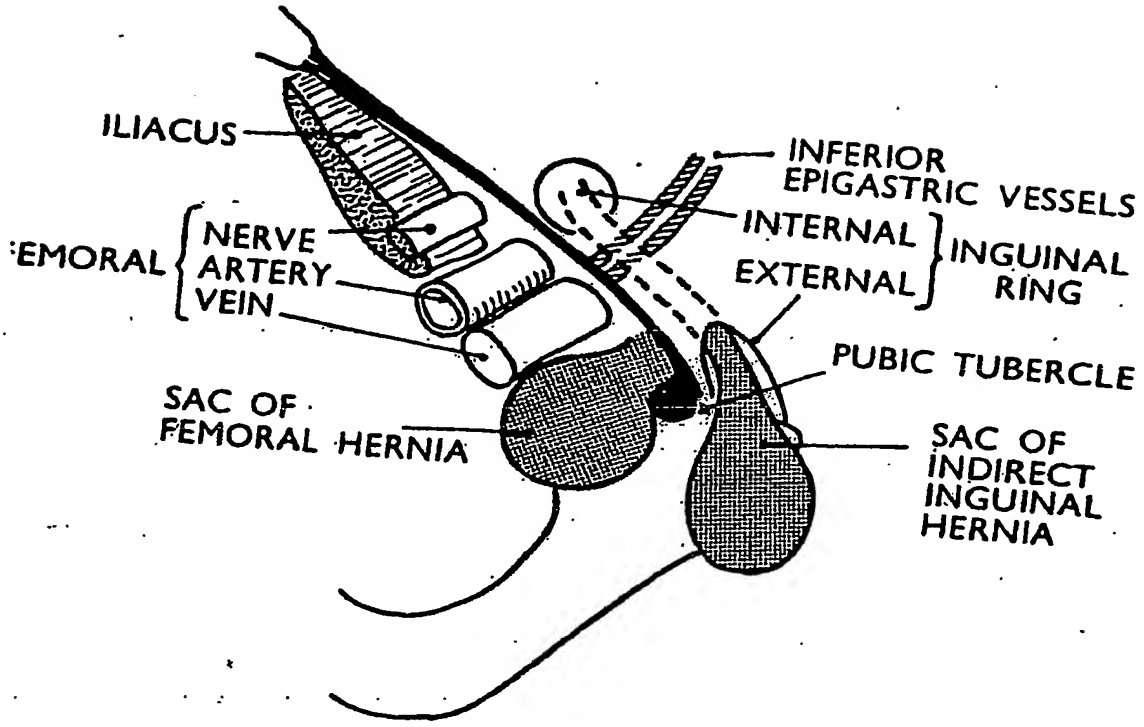


Figure 6


ILIACUS
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EPIGASTRIC VESSELS
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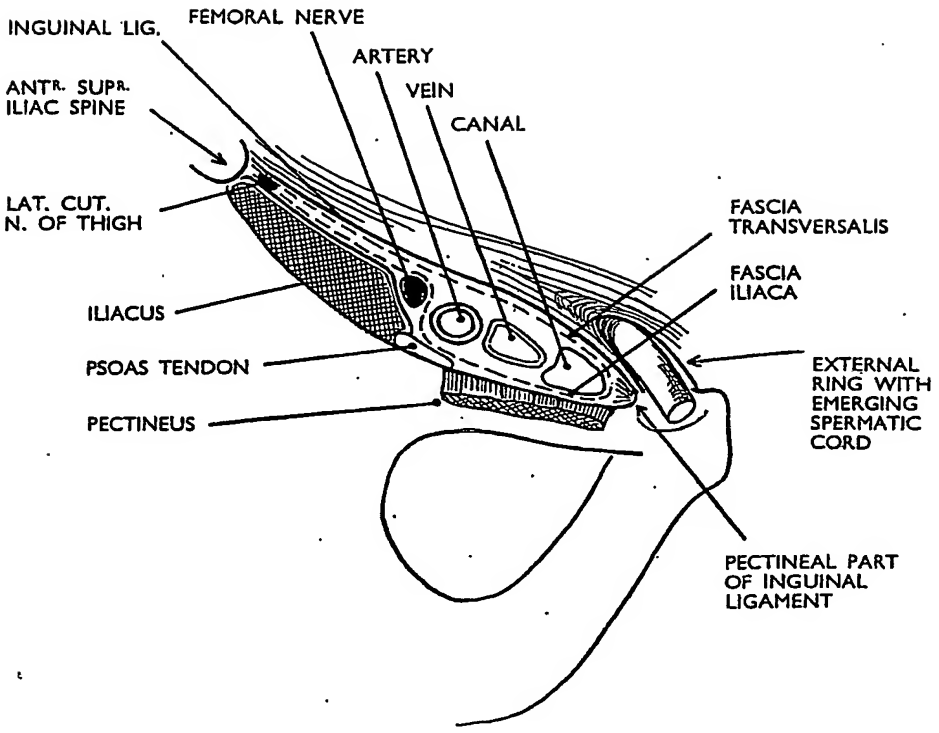
INDIRECT
INGUINAL
HERNIA

Figure 7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FEMORAL NERVE
ARTERY
VEIN
CANAL
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FASCIA TRANSVERSALIS
FASCIA ILIACA
ILIACUS
PSOAS TENDON
EXTERNAL RING WITH EMERGING SPERMATIC CORD
PECTINEUS
PECTINEAL PART OF INGUINAL LIGAMENT

Figure 8